

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

GLEND A JOHNSON, ET AL.

Plaintiffs,

V.

SMITHKLINE BEECHAM
CORPORATION, ET AL.

Defendants.

Case No: 2:11-cv-05782

AND ALL RELATED CASES

This Document Relates to:

DARREN GRIGGS, ET AL.

Plaintiffs,

V.

GLAXOSMITHKLINE LLC, ET AL.

Defendants.

Case No. 2:14-cv-02186

**ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS
GLAXOSMITHKLINE LLC AND GLAXOSMITHKLINE HOLDINGS
(AMERICAS) INC. TO THE COMPLAINT**

Defendants GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc.
(collectively, the “GSK Companies”), by and through their undersigned counsel, hereby answer
the Complaint as follows:

I. INTRODUCTION

1. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies admit only that thalidomide was developed by the German pharmaceutical company Grünenthal GmbH and are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations, and therefore deny the same.

2. The GSK Companies admit the link between thalidomide and certain birth defects was first reported in late 1961. The GSK Companies deny the allegations of the third sentence of this Paragraph as to Smith Kline & French (“SKF”) except that the GSK Companies admit that thalidomide was never approved by the FDA. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

3. The GSK Companies deny that SKF engaged in any of the acts alleged in this Paragraph and are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

4. The GSK Companies deny that SKF engaged in any misconduct as alleged in this Paragraph and are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same. By way of further response, information about thalidomide and its link to certain birth defects, as well as SKF’s investigation of thalidomide, has been publicly available for decades.

5. The allegations of this Paragraph are improper and require no response. To the extent that a response is required, the GSK Companies deny any allegations of misconduct in this

Paragraph and are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

6. The GSK Companies deny the allegations of this Paragraph as to SKF and are without knowledge or information sufficient to form a belief as to the remaining allegations of this Paragraph, and therefore deny the same.

7. Denied except that the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what mothers-to-be knew or did, and therefore deny the same.

8. The GSK Companies deny that SKF committed any acts of concealment, deny that SKF learned by 1958 that thalidomide caused birth defects, deny that SKF marketed thalidomide, deny that SKF lied to Congress, and deny that SKF knew prior to late 1961 of the dangers of thalidomide. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

9. The GSK Companies deny any allegations of a “cover up” in this Paragraph. The GSK Companies admit only that a GSK spokesperson made a statement in response to the allegations in the lawsuit captioned *Yeatts v. SmithKline Beecham Corp.*, filed in the Philadelphia Court of Common Pleas and removed to the U.S. District Court for the Eastern District of Pennsylvania but deny that such statement was in any way intended to “cover [its] role in the thalidomide tragedy.” By way of further response, the GSK spokesperson stated that SKF conducted animal studies and a clinical investigation of thalidomide, determined the drug was ineffective as a sedative, and never sought regulatory approval. Further, decades ago on August 27, 1962, SKF disclosed in a truthful letter to Congress that it had conducted a clinical

investigation of thalidomide involving approximately 875 patients and 67 investigators. SKF's correspondence was reported in a front page Washington Post article on September 9, 1962 and reprinted in the Congressional Record. Multiple newspaper and magazine articles, a book, and FDA investigation reports discussing SKF's clinical investigation have been in the public domain for decades. Moreover, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

10. The GSK Companies admit that Plaintiffs seek damages but deny that Plaintiffs' claims have any merit or factual or legal support and deny that Plaintiffs are entitled to any damages from the GSK Companies. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

- The allegations in this subpart of Paragraph 10 assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.
- The allegations in this subpart of Paragraph 10 are not directed to the GSK Companies. To the extent that the allegations of this subpart of Paragraph 10 are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.
- The GSK Companies deny the allegations of this subpart of Paragraph 10. By way of further response, on August 27, 1962, SKF disclosed in a

truthful letter to Congress that it had conducted a clinical investigation of thalidomide. SKF's correspondence was reported in a front page Washington Post article on September 9, 1962 and reprinted in the Congressional Record. Multiple newspaper and magazine articles, a book, and FDA investigation reports discussing SKF's clinical investigation have been in the public domain for decades. Moreover, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

- The allegations of this subpart of Paragraph 10 are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.
- The allegations in this subpart of Paragraph 10 assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

11. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

12. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

13. The GSK Companies deny the allegations of the second sentence of this Paragraph with regard to SKF's investigation of thalidomide. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

14. The GSK Companies deny the allegations in the last sentence of this Paragraph as to their or SKF's actions. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same. By way of further response, information about SKF's investigation of thalidomide was disclosed by SKF and has been publicly available for decades.

15. The GSK Companies deny the allegations of this Paragraph. By way of further response, information about thalidomide and its link to birth defects has been publicly available for decades.

II. THE PARTIES

A. Plaintiffs

1. Plaintiff Darren Griggs

16. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

17. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

18. Denied except that the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's or his family's knowledge, Plaintiff's alleged injuries, whether his alleged injuries were caused by thalidomide, and what his doctors told him, and therefore deny the same.

2. Plaintiff Carolyn Jean Grover

19. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

20. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

21. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies admit that thalidomide was never approved by the FDA but are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

3. Plaintiff William Tyler, III

22. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

23. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

24. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

B. Defendants

1. Defendant GlaxoSmithKline LLC

25. Denied except that GSK Companies admit that GlaxoSmithKline LLC is engaged in the development, testing, manufacturing, and marketing of pharmaceuticals. By way of further response, on October 27, 2009, the entity then known as SmithKline Beecham Corporation converted into GlaxoSmithKline LLC. GlaxoSmithKline LLC is a limited liability

company organized under Delaware law and the successor to SKF. The U.S. Court of Appeals for the Third Circuit has held that GlaxoSmithKline LLC is a citizen of Delaware.

26. The GSK Companies admit that GlaxoSmithKline LLC is the successor to SKF.

2. Defendant GlaxoSmithKline Holding (Americas) Inc.

27. Denied except that the GSK Companies admit that GlaxoSmithKline Holdings (Americas) Inc. is a Delaware corporation, a holding company, and the sole member of GlaxoSmithKline LLC. By way of further response, GlaxoSmithKline Holdings (Americas) Inc. is a Delaware corporation with its principal place of business in Wilmington, Delaware. The U.S. Court of Appeals for the Third Circuit has held that GlaxoSmithKline Holdings (Americas) Inc. is a citizen of Delaware.

3. Defendant Sanofi-Aventis, U.S. LLC

28. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

4. Defendant Grünenthal GmbH

29. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

III. JURISDICTION AND VENUE

30. Admitted.

31. Denied except that the GSK Companies admit that SKF tested thalidomide and conducted a clinical investigation of thalidomide involving approximately 875 patients and 67 investigators. The GSK Companies deny the characterization of SKF's clinical investigation in this Paragraph and any insinuation of wrongdoing. The remaining allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny those allegations.

32. Denied except that the GSK Companies admit that GlaxoSmithKline LLC is the successor to SKF and that SKF tested thalidomide and conducted a clinical investigation of thalidomide involving approximately 875 patients and 67 investigators. The GSK Companies deny the characterization of SKF's clinical investigation in this Paragraph and any insinuation of wrongdoing. The remaining allegations in paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny those allegations.

33. Denied except that the GSK Companies admit that GlaxoSmithKline Holdings (Americas) Inc. is the sole member of GlaxoSmithKline LLC. By way of further response, GlaxoSmithKline Holdings (Americas) Inc. is a Delaware corporation with its principal place of business in Wilmington, Delaware. The U.S. Court of Appeals for the Third Circuit has held that GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc. are both citizens of Delaware. The remaining allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny those allegations.

34. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

35. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same, except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956 and that SKF obtained the compound from Grünenthal GmbH for use in SKF's investigation of thalidomide.

36. Denied except that the GSK Companies admit that SKF tested thalidomide and conducted a clinical investigation of thalidomide involving approximately 875 patients and 67 investigators. The GSK Companies deny the characterization of SKF's clinical investigator in this Paragraph and any insinuation of wrongdoing. By way of further response, GlaxoSmithKline LLC is the successor to SKF. The U.S. Court of Appeals for the Third Circuit has held that GlaxoSmithKline LLC is a citizen of Delaware. The remaining allegations in paragraph are conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny those allegations.

IV. STATEMENT OF FACTS

A. Grünenthal and Thalidomide

37. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

38. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

39. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

40. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

41. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

42. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

43. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

44. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

45. The GSK Companies deny Plaintiffs' characterization and description of thalidomide embryopathy and what "should have been known" except that the GSK Companies admit that thalidomide is a teratogenic agent.

B. "Clinical Trials" in the United States

46. The GSK Companies deny the allegations in the second sentence of this Paragraph as to SKF except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956, that SKF conducted animal testing and a clinical investigation of thalidomide, and that SKF discontinued its investigation of thalidomide. By way of further response, on August 27, 1962, SKF disclosed in a truthful letter to Congress that it discontinued its investigation of thalidomide because the drug offered no significant clinical advantages over already available compounds. SKF's correspondence to Congress is reprinted in the Congressional Record. Further, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

47. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

48. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

49. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

50. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

51. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

52. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

53. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

54. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

55. Denied except that the GSK Companies admit that SKF conducted a clinical investigation of thalidomide. The GSK Companies deny the characterization of SKF's clinical investigation in this Paragraph and any insinuation of wrongdoing. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

56. Denied except that the GSK Companies admit that SKF conducted a clinical investigation of thalidomide. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

57. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

58. The GSK Companies cannot fully discern the allegations of the last sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

59. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

60. The GSK Companies cannot fully discern the allegations of the second sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

C. Thalidomide Injuries

61. The allegations of this Paragraph are improper and require no response. To the extent that a response is required, the GSK Companies admit that thalidomide and its link to birth defects was highly publicized in the United States and worldwide.

62. The allegations of this Paragraph are improper and require no response. To the extent that a response is required, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

63. The allegations of this Paragraph are improper and require no response. To the extent that a response is required, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

64. The GSK Companies cannot fully discern the allegations of the first sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

65. The GSK Companies cannot fully discern the allegations of the third sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

66. The allegations of this Paragraph are improper and require no response. To the extent that a response is required, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

D. Defendants fraudulently convinced Congress and the public that thalidomide could not have caused injuries in the United States, falsely claiming that it was almost entirely unavailable in the United States and failing to disclose that testing on pregnant women here had resulted in the births of at least two malformed babies by 1958.

67. The GSK Companies deny the allegations in the heading preceding Paragraph 67 as to SKF. Moreover, the allegations of this Paragraph do not accurately, fairly or completely describe the sources or documents cited. The GSK Companies are without knowledge or

information sufficient to form a belief as to the truth of the remaining allegations in this Paragraph, and therefore deny the same. By way of further response, information about the clinical trials of thalidomide in the United States has been publicly available for decades.

68. The GSK Companies deny that SKF made any false representations about usage of thalidomide in the United States and are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

69. Denied except that the GSK Companies admit that SKF declined to market thalidomide because it offered no significant clinical advantages over already available compounds. By way of further response, on August 27, 1962, SKF disclosed in a truthful letter to Congress that it had conducted a clinical investigation of thalidomide involving approximately 875 patients and 67 investigators. SKF's correspondence was reported in a front page Washington Post article on September 9, 1962 and reprinted in the Congressional Record. Multiple newspaper and magazine articles, as well as a book discuss SKF's clinical investigation. The FDA investigated SKF's clinical investigation and concluded that "there was nothing in [SKF's] file to suggest that this clinical investigation was other than a bona-fide study." SKF's correspondence to Congress, the articles, the book, and the FDA investigation reports have been in the public domain for decades.

70. The GSK Companies deny the allegations of this Paragraph. By way of further response, on August 27, 1962, SKF disclosed in a truthful letter to Congress that it had conducted a clinical investigation of thalidomide. SKF's correspondence to Congress is reprinted in the Congressional Record and is thus not "unreported." Moreover, in addition to the front page Washington Post article on September 9, 1962, multiple newspaper and magazine

articles, as well as a book discuss SKF's clinical investigation of thalidomide. The relationship between SKF and Grünenthal GmbH was also disclosed in publicly-available FDA documents. SKF's correspondence to Congress, the articles, the book, and the FDA investigation reports have been in the public domain for decades. Moreover, SKF's President did not lie to Congress.

71. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

72. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

73. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

E. Defendants successfully and fraudulently convinced Congress and the public that they did nothing illegal in developing thalidomide and distributing it in the United States.

74. The GSK Companies deny the allegations in the heading preceding Paragraph 74 and deny the allegations of the first sentence of this Paragraph as to SKF. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

75. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

76. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

77. Denied except that the GSK Companies admit that SKF President Walter Munns issued a press release on August 23, 1962. The allegations of this Paragraph do not accurately, fairly or completely describe the cited document.

78. Denied except that the GSK Companies admit that there was no Freedom of Information Act or Internet in the United States in the 1950s or 1960s and are without knowledge or information sufficient to form a belief as to the truth of the allegations and the second and third sentences of this Paragraph, and therefore deny the same. By way of further response, correspondence from SKF to Congress that is reprinted in the Congressional Record, multiple newspaper articles, magazines, a book, and FDA investigation reports discussing SKF's clinical investigation of thalidomide have been in the public domain for decades.

79. The GSK Companies deny the allegations in the first sentence of this Paragraph as to SKF. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

80. The GSK Companies deny the allegations of the second sentence of this Paragraph as to SKF. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

F. Smith, Kline & French's 50-Year Secret: By 1958, at Least One of Its Study Subjects Had Given Birth To A Malformed Baby.

81. The GSK Companies deny the allegations in the heading immediately preceding Paragraph 81. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and when counsel "gained access to evidence," and therefore deny the same. Moreover, Plaintiffs do not accurately, fairly or completely describe the documents which are cited immediately following Paragraph 81. By way of further response, it is specifically denied that two babies suffering from thalidomide-related birth defects were born to participants in SKF's clinical investigation. Further, SKF did not conceal or otherwise keep "secret" its clinical investigation of thalidomide. Correspondence from SKF to Congress that is reprinted in the Congressional Record, multiple newspaper articles, magazines, a book, and FDA investigation reports discussing SKF's clinical investigation of thalidomide have been in the public domain for decades. Additionally, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

82. The GSK Companies deny the allegations of the second sentence of this Paragraph except that the GSK Companies admit that SKF learned of thalidomide from Grünenthal GmbH by April 1956 and that by April 1956 SKF and Grünenthal GmbH discussed

entering into a contract for the possible development and marketing of thalidomide within the United States. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

83. Denied except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956 and that SKF conducted its own investigation and testing of thalidomide. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958.

84. The GSK Companies cannot fully discern the allegations of the last sentence of this Paragraph. From what can be discerned, the GSK Companies deny the allegations of this Paragraph except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958.

85. The GSK Companies cannot fully discern the allegations of the last sentence of this Paragraph. From what can be discerned, the GSK Companies deny the allegations of this Paragraph except that the GSK Companies admit that after investigation SKF decided not to market the drug because it offered no significant clinical advantages over already available compounds. By way of further response, on August 27, 1962, SKF disclosed in a truthful letter to Congress that it had conducted a clinical investigation of thalidomide and that it had obtained the compound from Grünenthal GmbH. Moreover, SKF's correspondence was reported in a front page Washington Post article on September 9, 1962. Multiple newspaper and magazine articles, as well as a book discuss SKF's clinical investigation. The relationship between SKF and Grünenthal GmbH was also disclosed in publicly-available FDA documents. The FDA

investigated SKF's clinical investigation of thalidomide and concluded that "there was nothing in [SKF's] file which would indicate that the firm dropped this drug for any reason other than lack of efficacy as a tranquilizing agent for which the drug was being investigated" and that "there was nothing in [SKF's] file to suggest that this clinical investigation was other than a bona-fide study." SKF's correspondence to Congress, the articles, the book, and the FDA investigation reports have been in the public domain for decades.

86. The GSK Companies deny the allegations of this Paragraph. The allegations of this Paragraph do not accurately, fairly or completely describe the cited document. By way of further response, on August 27, 1962, SKF President Walter Munns sent to Senator Hubert Humphrey a truthful letter in which he disclosed information relating to SKF's investigation of thalidomide. This letter stated that SKF performed "studies involving a total of approximately 700 animals of five species, namely, mice, rats, dogs, guinea pigs, and monkeys" and that SKF "completed animal studies on acute toxicity does range and pharmacological activities in October 1956." As was stated in the August 27, 1962 letter, SKF discontinued its investigation as the drug offered no significant clinical advantage over already available compounds. This correspondence is reprinted in the Congressional Record and was referenced in a front page Washington Post article on September 9, 1962 and subsequent press reports. SKF's correspondence to Congress and the Washington Post article have been in the public domain for decades.

87. Denied except that the GSK Companies admit that in his letter to Congress on August 27, 1962, Walter Munns stated that "[n]o testing was done on pregnant animals" in connection with SKF's investigation of thalidomide. The GSK Companies are without

knowledge or information sufficient to form a belief as to the truth of the allegations regarding “other drug companies,” and therefore deny the same.

88. The Companies cannot fully discern the allegations of the first sentence of this Paragraph. From what can be discerned, the GSK Companies deny the allegations of this Paragraph except that the GSK Companies admit that in his letter to Congress on August 27, 1962, Walter Munns disclosed that SKF had conducted a clinical investigation of thalidomide involving approximately 875 patients and 67 investigators. By way of further response, SKF’s correspondence to Congress is reprinted in the Congressional Record. Moreover, SKF’s correspondence was reported in a front page Washington Post article on September 9, 1962. Multiple newspaper and magazine articles, as well as books discuss SKF’s clinical investigation of thalidomide. The FDA investigated SKF’s clinical investigation and concluded that “there was nothing in [SKF’s] file to suggest that this clinical investigation was other than a bona-fide study.” SKF’s correspondence to Congress, the articles, the books, and the FDA investigation reports have been in the public domain for decades. Further, SKF’s clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

89. Denied except that the GSK Companies admit that part of SKF’s clinical investigation of thalidomide involved a survey group called “hawk.” The GSK Companies deny Plaintiffs’ description and characterization of SKF’s clinical investigation of thalidomide.

90. Denied except that the GSK Companies admit that part of SKF’s clinical investigation of thalidomide involved a survey group called “hawk” and that SKF’s clinical investigation primarily involved pediatric and geriatric patients, not pregnant women. By way further response, SKF did not “experiment[] on humans to determine toxicity” but instead

conducted a clinical investigation in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

91. The GSK Companies admit only that SKF identified thalidomide as SKF #5627 to its clinical investigators but deny any insinuation that SKF hid the fact that the drug was thalidomide.

92. The GSK Companies cannot fully discern the allegations of this Paragraph. From what can be discerned, the allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the FDA regulations then in effect for a correct and complete statement of their provisions.

93. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

94. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

95. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

96. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

97. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

98. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

99. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

100. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

101. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the

allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

102. The GSK Companies deny the allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

103. The GSK Companies deny the allegations in the first and third sentences of this Paragraph except that GSK Companies admit that a New Drug Application was not pending during the period that SKF conducted a clinical investigation of thalidomide in 1956-57. The remaining allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that a response is required, the GSK Companies deny the remaining allegations of this Paragraph and refer to the statutes and FDA regulations then in effect for a correct and complete statement of their provisions.

104. Denied except that the GSK Companies admit that in 1962 SKF contacted its investigators to ensure that no supplies of thalidomide remained in their possession.

105. Denied except that the GSK Companies admit only that SKF required investigators to complete an investigator form in accordance with FDA regulations then in effect and that a statement that the forms had been destroyed appears in an FDA report dated September 26, 1962 made in connection with FDA's investigation of SKF's involvement with thalidomide. However, the GSK Companies are without knowledge at this time as to whether such forms were destroyed and, if so, when.

106. The GSK Companies admit only that SKF identified thalidomide as SKF #5627 to its clinical investigators but deny any insinuation that SKF hid the fact that the drug was thalidomide. The GSK Companies are without knowledge or information sufficient to form a

belief as to the truth of the allegations in the second sentence of this Paragraph, and therefore deny the same.

107. The GSK Companies deny the allegations of this Paragraph and deny that Plaintiffs' mothers were SKF clinical trial participants. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

108. The GSK Companies deny the allegations of this Paragraph. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

109. The GSK Companies deny the allegations of this Paragraph. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

110. Denied except that the GSK Companies admit that Walter Munns provided truthful and accurate answers in his letter dated August 27, 1962 to questions asked by Senator Hubert Humphrey in a letter dated August 21, 1962 relating to SKF's investigation of thalidomide. The allegations of this Paragraph do not accurately, fairly or completely describe the cited document.

111. Denied except that the GSK Companies admit that in his August 27, 1962 letter to Congress, Walter Munns truthfully disclosed that SKF had not observed any "effect which might be characterized as phocomelia or akin thereto" during its clinical investigation of thalidomide. The allegations of this Paragraph do not accurately, fairly or completely reflect the contents of the cited letter.

112. The GSK Companies deny the allegations of this Paragraph. By way of further response, Walter Munns' August 27, 1962 letter was reported in a front page Washington Post article on September 9, 1962 and thus was not a "news non-event." Moreover, multiple newspaper and magazine articles, as well as books discuss the SKF clinical investigation and have been in the public domain for decades. Further, Walter Munns did not lie to Congress.

113. Denied except that the GSK Companies admit that the cited documents are publicly available. The allegations of this Paragraph do not accurately, fairly or completely describe the cited documents. By way of further response, neither the August 13, 1962 memorandum nor the September 5, 1962 memorandum contains a conclusion with respect to the connection between any alleged malformations and SKF's clinical investigation of thalidomide. Moreover, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects. The GSK Companies are without knowledge or information sufficient to form a belief as to the allegations regarding when Plaintiffs' counsel located the August 13, 1962 memorandum, and therefore deny the same.

114. The GSK Companies cannot fully discern the allegations of this Paragraph. From what can be discerned, the GSK Companies deny the allegations of this Paragraph. The allegations of this Paragraph do not accurately, fairly or completely describe the cited document. By way of further response, the August 13, 1962 memorandum describes a request by a physician and his patient to keep their identities anonymous in the course of the FDA's investigation of SKF's involvement with thalidomide and SKF's communication to FDA of that request.

115. The GSK Companies deny the allegations of this Paragraph.

116. The GSK Companies deny the allegations of the first sentence of this Paragraph and are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations, and therefore deny the same. The allegations of the first sentence of this Paragraph do not accurately, fairly or completely describe the cited document. By way of further response, in his August 27, 1962 letter to Congress, Walter Munns reported that “a few physicians continued to use the material to conclude their studies” after SKF discontinued investigation of the drug in December 1957. As was stated in its August 27, 1962 letter, SKF discontinued its investigation as the drug offered no significant clinical advantage over already available compounds.

117. The GSK Companies deny the allegations of this Paragraph. It is specifically denied that two babies suffering from thalidomide-related birth defects were born to participants in SKF’s clinical investigation. By way of further response, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

118. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the Companies deny the allegations of this Paragraph and refer to the FDA regulations then in effect for a correct and complete statement of their provisions. By way of further response, SKF’s clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

119. The GSK Companies cannot fully discern the allegations of the third sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph assert conclusions

of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph and refer to the FDA regulations then in effect for a correct and complete statement of their provisions. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

120. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph except that the GSK Companies admit that SKF was aware of and in compliance with FDA regulations in effect at the time that SKF conducted its investigation of thalidomide. The GSK Companies refer to the FDA regulations then in effect for a correct and complete statement of their provisions. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

121. Denied as to the allegations in the last sentence of this Paragraph except that the GSK Companies admit that in his August 27, 1962 letter to Congress, Munns reported that "[c]omplete reports of all animal and human studies were sent to Chemie Grünenthal at frequent intervals during S.K.&F.'s evaluation and upon its completion." The remaining allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the remaining allegations of this Paragraph.

122. The GSK Companies deny the allegations in this Paragraph as to SKF. It is specifically denied that two babies suffering from thalidomide-related birth defects were born to participants in SKF's clinical investigation. By way of further response, SKF had no knowledge

prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

123. Denied except that the GSK Companies admit that Walter Munns issued a public statement dated August 23, 1962, with an attached paper called “Thoughts on Thalidomide.” The allegations of this Paragraph do not accurately, fairly or completely describe the cited document.

124. The GSK Companies deny the allegations of this Paragraph.

125. The GSK Companies deny the allegations of this Paragraph. The allegations of this Paragraph do not accurately, fairly or completely describe the cited document. By way of further response, SKF neither engaged in wrongful conduct with respect to its clinical investigation of thalidomide nor did it conceal said investigation.

126. The Companies deny the allegations of this Paragraph. By way of further response, information about SKF’s investigation of thalidomide has been in the public domain for decades.

G. Richardson-Merrell was the North American face of thalidomide and Grünenthal’s partner in concealment.

127. The GSK Companies admit only that SKF declined to market thalidomide because it offered no significant clinical advantages over already available compounds. The remaining allegations of this Paragraph and the heading preceding Paragraph 127 are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph

and the heading preceding Paragraph 127 are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

128. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

129. The GSK Companies deny the allegations in the last two sentences of this Paragraph as to SKF except that the GSK Companies admit that based on information currently available to the GSK Companies, SKF did not conduct testing of thalidomide on pregnant animals before SKF's clinical trial of thalidomide. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

130. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

131. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

132. The GSK Companies deny the allegations of this Paragraph as to SKF.

H. Merrell experiments on pregnant women.

133. The allegations of this Paragraph and the preceding heading are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

134. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

135. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

136. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

137. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

138. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

139. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

140. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

141. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

142. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

143. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

144. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

145. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

146. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

147. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

148. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

149. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

150. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

151. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

152. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

153. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

154. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

155. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

156. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

157. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

158. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

159. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

160. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

161. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

162. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

163. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

164. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

165. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

166. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

167. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

168. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

169. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

170. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

171. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

172. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

173. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

174. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

175. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

176. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

177. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

178. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

179. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

180. The GSK Companies cannot fully discern the allegations of the last sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

181. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

182. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

183. The GSK Companies deny that SKF was part of any public relations campaign with Merrell and Grünenthal GmbH. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

184. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

185. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

186. The GSK Companies cannot fully discern the allegations of the first sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

187. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

188. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

189. The GSK Companies cannot fully discern the allegations of the first sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

190. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

191. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

192. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

193. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

194. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

195. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

196. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

197. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

198. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

199. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

200. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

201. The GSK Companies cannot fully discern the allegations of the second sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

I. Drug developer and manufacturer Grünenthal, a Nazi-lead company whose motto was “succeed at any cost,” knew that thalidomide could cause birth defects by 1956 but never revealed that risk.

202. The allegations of this Paragraph and the preceding heading are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

203. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

204. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

205. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

206. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

207. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

208. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

209. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

210. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

211. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

212. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

213. Denied as to the allegations in the second and third sentences of this Paragraph as to SKF except that the GSK Companies admit that based on information currently available to the GSK Companies, SKF did not conduct testing of thalidomide on pregnant animals before SKF's clinical investigation of thalidomide. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore

214. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

215. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

216. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

217. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

218. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

219. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

220. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

221. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

222. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

223. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

224. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

225. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

226. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

227. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

228. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

229. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

230. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

231. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

232. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

233. The GSK Companies deny that two babies suffering from thalidomide-related birth defects were born to participants in SKF's clinical investigation. By way of further response, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

234. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

235. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

236. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

237. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

238. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

239. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

240. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

241. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

242. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

243. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

244. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

245. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

246. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

247. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

248. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

249. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

250. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

251. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

252. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

253. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

254. The GSK Companies cannot fully discern the allegations of the third sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

255. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

256. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

257. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

258. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

259. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

260. The GSK Companies cannot fully discern the allegations of the fourth sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

261. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

262. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

263. Denied as to the allegations of the first sentence of this Paragraph except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

264. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

265. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

266. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

267. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

268. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

269. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

270. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

271. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

272. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

273. The GSK Companies cannot fully discern the allegations of the last sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

274. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

275. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

276. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

277. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

278. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

279. The GSK Companies cannot fully discern the allegations of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

280. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

281. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

282. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

283. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

284. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

285. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

286. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

287. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

288. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

289. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

290. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

291. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

292. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

293. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

294. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

295. The GSK Companies deny that SKF “accelerated” or otherwise participated in any “campaign of disinformation and concealment” regarding thalidomide. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

296. The GSK Companies deny the allegations of this Paragraph as to SKF. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

297. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

298. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

299. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

300. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

301. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

302. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

303. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph, and therefore deny the same.

304. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

305. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK

Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

306. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

307. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

308. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

309. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE AND NEGLIGENT DESIGN

(All Defendants)

310. The GSK Companies repeat and incorporate by reference their responses to all preceding paragraphs of this Answer as if fully set forth herein.

311. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

312. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

313. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

314. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

315. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

316. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

317. The GSK Companies deny the allegations in the first sentence of this Paragraph as to SKF and are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

318. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

319. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

320. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

321. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

322. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

323. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

324. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

325. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

326. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

327. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

328. The GSK Companies deny the allegations of this Paragraph as to SKF.

329. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

- (a) The GSK Companies deny the allegations of subpart (a) as to SKF. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of subpart (a), and therefore deny the same.

- (b) The GSK Companies deny the allegations of subpart (b) as to SKF. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of subpart (b), and therefore deny the same.
- (c) The GSK Companies deny the allegations of subpart (c) as to SKF. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of subpart (c), and therefore deny the same.
- (d) The GSK Companies deny the allegations of subpart (d).
- (e) The GSK Companies admit only that based on information currently available to the GSK Companies, SKF did not conduct testing of thalidomide on pregnant animals before SKF's clinical investigation of thalidomide. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of subpart (e), and therefore deny the same.
- (f) The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations of subpart (f), and therefore deny the same.
- (g) The GSK Companies deny the allegations of subpart (g) as to SKF.
- (h) The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations in subpart (h), and therefore deny the same.

- (i) The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations in subpart (i), and therefore deny the same.
- (j) The GSK Companies deny the allegations of subpart (j).
- (k) Denied as to SKF except that the GSK Companies admit that SKF understood the need to establish the safety of any drug, through clinical investigation or otherwise, before marketing the drug. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in subpart (k), and therefore deny the same.
- (l) Denied as to SKF except the GSK Companies admit that based on information currently available to the GSK Companies, SKF did not conduct testing of thalidomide on pregnant animals before SKF's clinical investigation of thalidomide. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in subpart (l), and therefore deny the same.
- (m) The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the allegations in subpart (m), and therefore deny the same.
- (n) The GSK Companies deny the allegations of subpart (n) as to SKF. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of subpart (n), and therefore deny the same.

- (o) The GSK Companies deny the allegations of subpart (o) as to SKF. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of subpart (o), and therefore deny the same.
- (p) The GSK Companies deny the allegations of subpart (p) as to SKF. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of subpart (p), and therefore deny the same.
- (q) The GSK Companies deny the allegations of the last sentence of subpart (q) as to SKF. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in subpart (q), and therefore deny the same.
- (r) The first two sentences of subpart (r) assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations in the first two sentences of subpart (r) and refer to the FDA regulations then in effect for a correct and complete statement of their provisions. The GSK Companies deny the allegations of the last sentence of subpart (r) as to SKF and are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of the last sentence of subpart (r), and therefore deny the same. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of

the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

(s) The GSK Companies deny the allegations of subpart (s) as to SKF. The GSK Companies are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of subpart (s), and therefore deny the same. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

(t) The GSK Companies deny that SKF did not comply with the law then in effect, deny that SKF acted unethically, and deny the characterization of what SKF told its investigators. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

330. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

331. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

332. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

SECOND CAUSE OF ACTION

FRAUD AND NEGLIGENT MISREPRESENTATION

(Against Grünenthal and Sanofi-Aventis)

333. The GSK Companies repeat and incorporate by reference their responses to all preceding paragraphs of this Answer as if fully set forth herein.

334. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

335. The allegations of this Paragraph, including its subparts, are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies deny that SKF engaged in any fraudulent acts in connection with its investigation of thalidomide.

336. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies deny the allegations of this Paragraph as to SKF.

337. The GSK Companies cannot fully discern the allegations of the last sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies deny the allegations of this Paragraph as to SKF.

338. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies deny the allegations of this Paragraph as to SKF except that to the extent that the documents cited in this Paragraph exist, the GSK Companies refer to those documents for a fair, accurate and complete description of their contents. By way of further response, information about thalidomide and its link to certain birth defects, as well as SKF's clinical investigation of thalidomide, has been publicly available for decades.

339. The GSK Companies cannot fully discern the allegations of the first sentence of this Paragraph. From what can be discerned, the allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies deny the allegations of this Paragraph as to SKF.

340. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies deny the allegations of this Paragraph as to SKF.

341. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

THIRD CAUSE OF ACTION

FRAUD AND/OR NEGLIGENT MISREPRESENTATION

(Against GSK Defendants)

342. The GSK Companies repeat and incorporate by reference their responses to all preceding paragraphs of this Answer as if fully set forth herein.

343. The GSK Companies deny the allegations of this Paragraph and incorporate by reference their answers to each of the allegations in the Statement of Facts of this Answer as if fully set forth herein.

- 1) The GSK Companies deny the allegations of subpart (1). By way of further response, SKF neither concealed nor misrepresented its testing of thalidomide. The Congressional Record, multiple newspaper and magazine articles, as well as a book disclose SKF's clinical investigation. The FDA investigated SKF's clinical investigation and concluded that "there was nothing in [SKF's] file to suggest that this clinical investigation was other than a bona-fide study." SKF's correspondence to Congress, the articles, the book, and the FDA investigation reports have been in the public domain for decades. Moreover, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.
- 2) The GSK Companies deny the allegations of subpart (2). By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.
- 3) The GSK Companies deny the allegations of subpart (3). It is specifically denied that two babies suffering from thalidomide-related birth defects were born to participants in SKF's clinical investigation. By way of further response, SKF neither concealed nor misrepresented its testing of thalidomide. The Congressional Record, multiple newspaper and magazine articles, as well as a book disclose SKF's clinical investigation. The FDA investigated SKF's clinical investigation and concluded that "there was nothing in [SKF's] file to suggest that this clinical investigation was other than a bona-fide study." SKF's correspondence to Congress, the articles, the book, and the FDA investigation reports have been in the public domain for decades. Moreover, SKF's President did not lie to Congress.

- 4) The GSK Companies deny the allegations of subpart (4). By way of further response, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.
- 5) The GSK Companies deny the allegations of subpart (5).
- 6) The GSK Companies deny the allegations of subpart (6).
- 7) Denied except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956 and that SKF obtained the compound from Grünenthal GmbH. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958. Moreover, on August 27, 1962, SKF disclosed in a truthful letter to Congress that it had conducted a clinical investigation of thalidomide and that it had obtained the compound from Grünenthal GmbH. The relationship between SKF and Grünenthal GmbH was also disclosed in publicly-available FDA documents. SKF's correspondence to Congress, which is reprinted in the Congressional Record, and the FDA documents have been in the public domain for decades.
- 8) Denied except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958. Moreover, on August 27, 1962, SKF disclosed in a truthful letter to Congress that it had conducted a clinical investigation of thalidomide and that it had obtained the compound from Grünenthal GmbH. The relationship between SKF and Grünenthal GmbH was also disclosed in publicly-available FDA documents. SKF's correspondence to Congress, which is reprinted in the Congressional Record, and the FDA documents have been in the public domain for decades.

9) The GSK Companies deny the allegations of subpart (9).

10) The GSK Companies deny the allegations of subpart (10).

344. Denied except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958.

345. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956 and that it obtained the compound from Grünenthal GmbH. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958.

346. The GSK Companies deny the allegations of this Paragraph.

347. The Companies deny the allegations of this Paragraph. By way of further response, there is no evidence that any of the Plaintiffs, any of their mothers, or any of the physicians who purportedly dispensed thalidomide to their mothers relied on any SKF results to dispense, administer or ingest thalidomide. SKF declined to market the drug and terminated the preliminary licensing agreement with Grünenthal GmbH on January 17, 1958. There is no evidence that anyone in fact relied on the SKF clinical investigator to form any conclusions about the safety of thalidomide.

348. Denied except that the GSK Companies admit that information regarding the safety of any drug is important information.

349. The allegations in paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph. By way of further response, SKF President Walter Munns provided truthful and accurate answers in his letter of August 27, 1962 to questions asked by Senator Hubert Humphrey in correspondence dated August 21, 1962 relating to SKF's investigation of thalidomide. Moreover, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

350. The allegations of this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

351. The GSK Companies deny the allegations of this Paragraph. By way of further response, SKF was not silent about the association between thalidomide and birth defects. SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

352. The GSK Companies deny the allegations of this Paragraph. By way of further response, SKF President Walter Munns provided truthful and accurate answers in his letter of August 27, 1962 to questions asked by Senator Hubert Humphrey in correspondence dated August 21, 1962 relating to SKF's investigation of thalidomide.

353. The GSK Companies deny the allegations of this Paragraph. By way of further response, SKF did not suppress information regarding its clinical investigation of thalidomide. SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical

participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

354. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph. By way of further response, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

355. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph. By way of further response, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

356. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph. By way of further response, SKF did not conceal and has not concealed that it conducted a clinical investigation of thalidomide. SKF's correspondence to Congress, articles, a book, and the FDA investigation reports discussing SKF's clinical investigation have been in the public domain for decades.

357. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

358. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph. By way of further response, SKF's correspondence to Congress, articles, a book, and the FDA investigation reports discussing SKF's clinical investigation have been in the public domain for decades.

FOURTH CAUSE OF ACTION

NEGLIGENT HIRING

(Against Grünenthal)

359. The GSK Companies repeat and incorporate by reference their responses to all preceding paragraphs of this Answer as if fully set forth herein.

360. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations of this Paragraph, and therefore deny the same.

361. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations of this Paragraph, and therefore deny the same.

362. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations of this Paragraph, and therefore deny the same.

363. The allegations of this Paragraph, including its subparts, are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK

Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations of this Paragraph, and therefore deny the same.

364. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations of this Paragraph, and therefore deny the same.

365. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations of this Paragraph, and therefore deny the same.

FIFTH CAUSE OF ACTION

CONCERT OF ACTION

(Against All Defendants)

366. The GSK Companies repeat and incorporate by reference their responses to all preceding paragraphs of this Answer as if fully set forth herein.

367. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

368. The allegations in this Paragraph are denied as to SKF except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956. By way of further response, there is no evidence that SKF acted in concert with anyone. It entered a preliminary licensing agreement so it could evaluate whether it should bring thalidomide to the U.S. market. It soon concluded the drug offered no

significant clinical advantages over already available compounds, terminated its clinical investigation, terminated the preliminary licensing agreement on January 17, 1958, and thereby declined to bring thalidomide to the market. Everything that happened thereafter was the result of the actions of distinct entities, who did not act in concert with SKF.

369. The GSK Companies deny the allegations of this Paragraph as to SKF.

370. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects.

371. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

372. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

373. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

SIXTH CAUSE OF ACTION

CIVIL CONSPIRACY

(All Defendants)

374. The GSK Companies repeat and incorporate by reference their responses to all preceding paragraphs of this Answer as if fully set forth herein.

375. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

376. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

377. Denied except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958.

378. Denied except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958.

379. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

380. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the allegations of this Paragraph are denied as to SKF except that the GSK Companies admit that SKF and Grünenthal GmbH entered into a preliminary licensing agreement dated July 28, 1956. By way of further response, SKF terminated the preliminary licensing agreement on January 17, 1958, effective February 28, 1958.

381. The GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF did not “participat[e] in a human experiment.” The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

382. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph as to SKF.

383. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

384. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

VI. PUNITIVE DAMAGES

385. The GSK Companies repeat and incorporate by reference their responses to all preceding paragraphs of this Answer as if fully set forth herein.

386. The GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

387. The GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

388. The GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

389. The GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

390. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

391. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

392. The GSK Companies deny the allegations in the first, third, and fourth sentences of this Paragraph as to SKF. By way of further response, SKF had no knowledge prior to 1962 of any reports of children with birth defects born to clinical participants involved in its investigation of thalidomide and/or the possible connection between thalidomide and said birth defects. Moreover, SKF's President Walter Munns did not lie to Congress. Munns provided truthful and accurate answers in his letter of August 27, 1962 to questions asked by Senator Hubert Humphrey in correspondence dated August 21, 1962 relating to SKF's investigation of thalidomide. The remaining allegations of this Paragraph are not directed to the GSK Companies. To the extent that the remaining allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those remaining allegations, and therefore deny the same.

393. The allegations of this Paragraph are not directed to the GSK Companies. To the extent that the allegations of this Paragraph are directed to the GSK Companies, the GSK Companies are without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore deny the same.

394. The GSK Companies deny the allegations of this Paragraph as to SKF.

395. The GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

396. The GSK Companies deny the allegations of this Paragraph as to SKF. By way of further response, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge at the time and FDA regulations then in effect.

397. The allegations in this Paragraph assert conclusions of law and, accordingly, no response is required. To the extent that any response is required, the GSK Companies deny the allegations of this Paragraph.

PRAYER FOR RELIEF

The GSK Companies admit only that Plaintiffs seek the relief requested but deny that Plaintiffs are entitled to any relief in this lawsuit.

AFFIRMATIVE DEFENSES

The GSK Companies assert the following affirmative defenses in response to the allegations in Plaintiffs' Complaint:

1. Plaintiffs' claims, based on events that occurred more than 50 years ago and that were the subject of a massive media blitz in the early 1960s and beyond, are time-barred on the face of the Complaint.
2. Plaintiffs' claims are barred by the applicable statute of limitations.
3. Plaintiffs' claims are barred by the applicable statute of repose.
4. Plaintiffs' Complaint fails to state a claim upon which relief may be granted.
5. Plaintiffs' claims should be dismissed due to improper venue and/or pursuant to the doctrine of forum non conveniens.
6. Plaintiffs' claims are barred by the doctrine of laches.
7. The GSK Companies plead collateral estoppel, res judicata, waiver, and failure to mitigate or minimize damages, if any.
8. Plaintiffs' claims are improperly joined because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences.

9. Plaintiffs' claims are controlled by state or other applicable law other than the Commonwealth of Pennsylvania, and Plaintiffs fail to state any claim upon which relief may be granted under applicable state or other law.

10. The alleged negligent or culpable conduct of the GSK Companies, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiffs' alleged injuries.

11. If Plaintiffs were injured and damaged, which injuries and damages are denied, such injuries and damages were the result of intervening or superseding events, factors, occurrences, or conditions, which were in no way caused by the GSK Companies and for which the GSK Companies are not responsible and not liable.

12. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not suffered any actual loss or damage as a result of any actions of the GSK Companies or any conspiracy as alleged in the Complaint.

13. No act or omission of the GSK Companies was malicious, willful, wanton, reckless, grossly negligent, or intentional, and therefore any award of punitive damages is barred.

14. At all relevant times involved, SKF's clinical investigation of thalidomide was in conformity with the state of the art and/or the state of scientific knowledge and FDA regulations then in effect.

15. Plaintiffs have failed to allege fraud, concealment, or misrepresentation with sufficient particularity.

16. Plaintiffs' claims are barred to the extent that Plaintiffs have released, settled, or otherwise compromised their claims.

17. Any verdict or judgment rendered against the GSK Companies must be reduced by those amounts that have or will, with reasonable certainty, replace, or indemnify Plaintiffs, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, Social Security, workers' compensation, or employee benefit programs.

18. Any imposition of punitive or exemplary damages in this case against the GSK Companies is barred to the extent that the manner in which such damages are calculated violates the Constitution of the United States or the applicable state Constitution.

19. Any award of punitive or exemplary damages in this case against the GSK Companies is barred to the extent that the amount of such an award violates the Constitution of the United States or the applicable state Constitution.

20. A claim for punitive or exemplary damages against the GSK Companies in this case cannot be sustained because any award of punitive or exemplary damages that is rendered without bifurcating the trial and trying all such damages issues after and only if liability is found on the merits would violate the GSK Companies' due process rights guaranteed by the Fourteenth Amendment to the United States Constitution, and would be improper under the common law and public policies of applicable state law.

21. Any claim for punitive or exemplary damages against the GSK Companies in this case cannot be sustained because any award of punitive or exemplary damages under applicable state law subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive or exemplary damages that a jury would impose would violate the GSK Companies' due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due process provisions of

the applicable state Constitution, and would be improper under the common law and public policies of applicable state law.

22. If acts, omissions or fault of other persons or entities for whom the GSK Companies have no liability caused Plaintiffs' alleged damages, then such acts, omissions or fault bar or limit any recovery from the GSK Companies, as provided by Pennsylvania law or other applicable law.

23. When SKF performed the conduct for which it is alleged to be liable in this case, it lacked adequate notice that it could be liable over 50 years later to strangers with whom SKF had no legal relationship. At the time SKF engaged in that conduct, no legal duty of the sort proposed in this case had been recognized. As such, the federal and state due process clauses preclude the imposition of liability on the GSK Companies, as do other constitutional limitations.

24. To the extent not stated above, the GSK Companies raise all affirmative defenses available under the law of the forum in which each respective claim arose.

25. The GSK Companies adopt by reference any other affirmative defense raised by other Defendants.

26. The GSK Companies reserve the right to assert additional defenses which may become available to them as investigation and discovery proceed.

WHEREFORE, the GSK Companies demand judgment in their favor and against Plaintiffs on all claims, together with attorneys' fees, costs of suit, and such other relief as the Court finds just and proper.

JURY DEMAND

The GSK Companies demand a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Michael T. Scott

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Dated: June 23, 2014

CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2014, a copy of this document was filed electronically and is available for viewing and downloading from the CM/ECF system. I also certify that a true and correct copy of the foregoing document is being served this day on all counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF.

/s/ Michael T. Scott
Michael T. Scott